UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 01-12257-PBS Subcategory Case No. 06-11337
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation* Civil Action No. 09-CV-10547	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

RELATOR VEN-CARE OF THE FLORIDA KEYS, INC.'S AMENDED COMPLAINT AGAINST SCHERING CORPORATION, SCHERING-PLOUGH CORP. AND WARRICK PHARMACEUTICALS CORP. FOR VIOLATIONS OF THE FALSE CLAIMS ACT, 31 U.S.C. §3729, et seq.

VEN-A-CARE OF THE FLORIDA KEYS INC. ("VEN-A-CARE" or the "Relator") brings this False Claims Action on behalf of the United States and on the Relator's own behalf, against SCHERING CORPORATION, SCHERING-PLOUGH CORP. and WARRICK PHARMACEUTICALS CORP., (hereinafter the "DEFENDANTS") to recover losses sustained by the Medicaid Programs arising out of DEFENDANTS' violations of the Federal False Claims Act ("False Claims Act" or the "Act") 31 U.S.C., §§3729-3732. Over the course of several years, DEFENDANTS reported inflated pharmaceutical prices that they knew Medicaid relied upon to set reimbursement rates for albuterol pharmaceutical products. The actual sales prices for albuterol, the prices generally and currently paid by Customers in the marketplace were far less than the prices reported by DEFENDANTS.

By knowingly reporting inflated prices - often two times and as much as seven times higher than prices generally and currently paid by Customers in the marketplace - DEFENDANTS ensured that their customers received inflated reimbursement and profits from Medicaid. DEFENDANTS thus used the public fisc as a marketing tool, by enabling and/or promoting government-funded "spreads" between their fraudulently inflated prices and their actual sales prices, to serve as an inducement to their customers to purchase the DEFENDANTS' drugs.

I. NATURE OF ACTION

1. Ven-A-Care brings this action on behalf of the United States to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33 as well as other monetary relief.

2. Ven-A-Care bases its claims on DEFENDANTS having presented or caused the presentation of false or fraudulent claims to the United States in violation of 31 U.S.C. §3729(a)(1), and having made or used false statements to get false or fraudulent claims paid by the Government in violation of 31 U.S.C. § 3729(a)(2).

3. Between December 1994 and at least April 2005, DEFENDANTS engaged in a fraudulent scheme that caused the Medicaid Programs to pay excessive reimbursement to their customers; *e.g.*, pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies and clinics (hereafter referred to collectively as "Customers"). In furtherance of this scheme, DEFENDANTS reported false, fraudulent and inflated drug prices for certain drugs to several national price reporting compendia that the Medicaid Programs relied upon to set reimbursement rates for DEFENDANTS' Customers. Charts setting out examples of the differences between the

prices at which DEFENDANTS actually sold the albuterol products at issue and the false prices reported by DEFENDANTS are attached hereto as **Exhibit A**. DEFENDANTS knew that the Medicaid Programs relied on DEFENDANTS' reported prices to the national pricing compendia to set reimbursement rates for claims submitted for albuterol solutions. DEFENDANTS then sold the drugs for far lower prices, and marketed, directly and indirectly, to existing and potential Customers the government-funded "spread" between the inflated reimbursement amounts and the Customers' actual acquisition costs of the drugs to boost DEFENDANTS' sales and profits.

4. DEFENDANTS knew that their false price reporting and marketing efforts would cause their Customers to submit claims for fraudulently inflated Medicaid reimbursement.

5. DEFENDANTS' fraudulent scheme to induce Customers to purchase their products by ensuring that Medicaid reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. §1320a-7b(b) and numerous state laws.

6. To get fraudulent claims paid by the Medicaid Program, DEFENDANTS also routinely made false statements by reporting these same fraudulently inflated prices directly to the states. These statements violated the FCA.

II. JURISDICTION

7. Jurisdiction is founded upon the Federal False Claims Act, 31 U.S.C. §3729-32, specifically 31 U.S.C. §3730, and also 28 U.S.C. §§1331, 1345.

8. Ven-A-Care's claims against DEFENDANTS in this matter were filed under

seal pursuant to 31 U.S.C. §3730 on August 13, 1997 in the Southern District of Florida in Case No. 95-1354 in front of United States District Judge Alan S. Gold. On December 4, 2008, Judge Gold ordered the claims against the DEFENDANTS severed from Case No. 95-1354 and ordered the Clerk of Court to assign a new civil action number for the management of the severed action.

9. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345. The Court may exercise personal jurisdiction over DEFENDANTS pursuant to 31 U.S.C. §3732(a) because DEFENDANTS reside or transact business in the Southern District of Florida.

10. The Relator has standing to bring and has brought this action on behalf of itself and the United States pursuant to 31 U.S.C. §3730.

III. VENUE

11. Venue is proper in the Southern District of Florida under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because DEFENDANTS reside or transact business in this District.

IV. PARTIES

12. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care's current principal officers and directors are John M. Lockwood, M.D., Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide the prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a

Medicare and Florida Medicaid provider.

13. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims. Ven-A-Care has brought this action against DEFENDANTS on behalf of itself and the United States.

14. The Relator, Ven-A-Care, became aware of DEFENDANTS' false claim scheme alleged herein due to its position as an industry insider. The Relator commenced its *qui tam* action against DEFENDANTS for the drugs at issue based upon its industry insider information. Ven-A-Care, as a pharmacy, has access to pricing information such as wholesaler and GPO catalogues and proprietary computer programs revealing the prices generally and currently available and paid in the marketplace, but not known to the general public or the Government. Ven-A-Care, as an industry insider, discovered huge profit spreads on the drugs at issue and that the drugs at issue were reimbursed by Medicaid at amounts that substantially exceeded, and in some cases exceeded by a multiple of two or three times and up to seven times the cost of the drugs. Ven-A-Care directly witnessed and observed the DEFENDANTS' use of the false, inflated prices and resulting spread to market their drugs. Ven-A-Care's principals were aware that Medicaid intended to reimburse for drugs at amounts based on an estimation of provider acquisition cost and did not intend Medicaid reimbursements to be based on false, inflated prices at the Government's expense.

15. The United States has declined to join the prosecution of this action, but remains a party to this action pursuant to 31 U.S.C. § 3730(c)(3). The United States has requested that it be supplied with copies of all pleadings filed in the action and copies of all deposition transcripts.

16. The DEFENDANT WARRICK PHARMACEUTICALS CORP. ("WARRICK"), is a corporation organized under the laws of Delaware with its purported principal offices at 12125 Moya Boulevard, Reno, Nevada. This facility is actually simply a warehouse owned and operated by another company; either SCHERING CORPORATION or SCHERING-PLOUGH CORPORATION. WARRICK conducts no business in these offices. SCHERING CORPORATION ("SCHERING"), a corporation organized under the laws of New Jersey with its principal offices in Kenilworth, New Jersey is the corporate parent of WARRICK. SCHERING-PLOUGH CORPORATION ("SCHERING-PLOUGH") is a corporation organized under the laws of New Jersey with its principal offices in Kenilworth, New Jersey and is the ultimate parent of WARRICK. SCHERING and SCHERING-PLOUGH are directly responsible for the alleged conduct of WARRICK because they controlled the conduct. Furthermore, SCHERING and SCHERING-PLOUGH are responsible for WARRICK'S conduct alleged herein because WARRICK is the alter ego of SCHERING and SCHERING-PLOUGH. Additionally WARRICK operated with SCHERING and SCHERING-PLOUGH in a *de facto* joint venture or single enterprise. WARRICK, SCHERING and SCHERING-PLOUGH are collectively referred to as "DEFENDANTS."

V. THE LAW

A. The False Claims Act

17. The FCA provides in pertinent part, that:

(a) Any person who (I) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be

> made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
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> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.
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> * * *
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (I) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

18. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996,28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

19. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of the Medicare and Medicaid programs. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

20. The anti-kickback statute prohibits any person or entity from making or

accepting any payment to induce or reward any person for referring, recommending or arranging for federally funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary

penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

VI.THE MEDICAID PROGRAM

21. Medicaid was created to provide access to healthcare for elderly, indigent or disabled residents of the United States.

22. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

23. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

24. The Medicaid programs of all states reimburse for prescription drugs.

25. The United States Government, through the Secretary of the United States Department of Health and Human Services, is required to pay to each state, for each calendar quarter, an amount equal to the Federal Medical Assistance Percentage ("FMAP") of the total amount expended by the state during the quarter as medical assistance under the state Medicaid plan pursuant to 42 U.S.C. § 1396b(a)(1).

26. The federal portion of States' Medicaid payments, Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. For example, Florida's FMAP contributed by the United States in the fiscal year October 1, 2003 to September 30, 2004 was 58.93%.

27. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

28. Each State Health Plan must, in part, provide a formula for payment of reimbursement claims for prescription drugs, and each state's plan must be approved by the Secretary of HHS. The formula determines the reimbursement amount the state plan will pay for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement, based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR §447.331. Under certain circumstances, the federal Center for Medicare and Medicaid Services ("CMS") may establish a "Federal Upper Limit," binding on all state plans, on the allowable reimbursement for a particular drug.

29. The states' methodologies for arriving at a provider's Estimated Acquisition Cost ("EAC") for each covered drug, as required by 42 CFR §447.331, must be approved by the Secretary of HHS.

30. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

31. To claim its FMAP payment, each state must submit a report to the United States Secretary of Health and Human Services reflecting its anticipated Medicaid expenses for the quarter. The Secretary is required to estimate the state's FMAP entitlement for the quarter, based on the state's report and such other investigation as the Secretary may find necessary, and pay that amount to the state in such installments as the Secretary may determine, adjusted for any overpayments or underpayments in prior quarters. 42 U.S.C. § 1396b(d)(1), (2A). The Secretary's determination of a

state's FMAP entitlement obligates any appropriations available for payments to the state. 42 U.S.C. § 1396b(d)(4).

32. DEFENDANTS knowingly reported false, inflated price and cost data for the Specified Drugs to the national pharmaceutical pricing compendia relied on by the states, or directly to the states, or both, and thereby caused the states to pay excessive reimbursement amounts for DEFENDANTS' Specified Drugs and in turn caused the claims submitted by each state to officers and employees of the UNITED STATES for FMAP to be greater than they would have been but for DEFENDANTS' false price representations. As a result, DEFENDANTS caused the United States to expend FMAPs in amounts greater than would have been expended, but for DEFENDANTS' false reports of price and cost data, and thus caused injury to the federal fisc.

33. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique II-digit, 3-segment number, known as the National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The Specified Drugs and corresponding NDCs at issue in this case (collectively referred to as the "Specified Drugs") were assigned a unique labeler code for WARRICK and are listed in **Exhibit A**.

34. Drug manufacturers, such as DEFENDANTS, have not typically submitted claims for reimbursement to federal health care programs. Instead, DEFENDANTS marketed their products to their Customers, who then purchased the products either directly or through wholesalers, such as Mckesson, Cardinal or Amerisource Bergen,

based on a price the Customers negotiated with DEFENDANTS. In addition to using wholesalers, Customers purchased the DEFENDANTS' products through group purchasing organizations ("GPO"), which negotiated prices on behalf of the DEFENDANTS' Customers. Customers also purchased the DEFENDANTS' products from speciality wholesalers or distributors which often offered equally competitive prices.

35. DEFENDANTS' Customers submitted claims for payment for the albuterol solution products to Medicaid after dispensing or administering the drugs.

36. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

37. Each of the claims at issue is a false claim, in part, because each was supported by, and the reimbursement amount was determined from, the false and misleading price information provided by DEFENDANTS in connection with the Specified Drugs. The claims at issue in this action are all claims for reimbursement submitted to Medicaid by or on behalf of DEFENDANTS' Customers (also referred to as health care "Providers") that sought and received payments in excessive amounts because of DEFENDANTS' false price reports. The claims at issue number in the tens of thousands and were submitted by thousands of Providers nationwide throughout the relevant time period of the Complaint. Each claim is in the possession of the state Medicaid program that received it.

38. During the relevant period, DEFENDANTS periodically reported prices for pharmaceuticals to various price publishers. The price publishers used the information to publish national pricing compendia that was widely used by Medicare, Medicaid and

private payors to determine reimbursement for pharmaceuticals.

39. The reimbursement amounts for claims submitted by DEFENDANTS' Customers for the Specified Drugs at issue in this Complaint were directly influenced by DEFENDANTS' false price representations. The information contained in the published national pricing compendia was used by most third party payer insurance companies, including the Medicare and Medicaid programs, in determining the reimbursement rates for prescription drugs. DEFENDANTS knew their false, inflated price representations resulted in inflated government reimbursements on claims submitted by their Customers for their Specified Drugs.

40. No governmental payor knew of or sanctioned DEFENDANTS' conduct as set forth in this Complaint; *i.e*., their deliberate manipulation of the published prices for certain of their products to induce their Customers to purchase those products.

41. When reimbursing for drugs, the Medicaid Program's goal has been to pay an amount which reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. To determine the EAC for a covered drug, State Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

42. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the provider's usual and

customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

43. The states' methodology for arriving at EAC includes:

A. discounting a percentage off of the Average Wholesale Price ("AWP");

B. adding a percentage to the Wholesale Acquisition Cost ("WAC")[1]; and/or,

C. requiring the drug companies to certify prices directly in writing to the Medicaid program.

44. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then dispenses or administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer. At all relevant times, manufacturers and others in the industry knew that Medicaid used published AWPs and/or WACs to estimate acquisition costs, defined as the best estimate of the price generally and currently paid by providers in the marketplace.

45. While the majority of states use published AWPs to calculate reimbursement, approximately five states (Alabama, Florida, Maryland, Massachusetts and Rhode Island) have used the wholesale acquisition cost ("WAC") to set the EAC.

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[1]Until approximately 2005, First DataBank published WAC, as “WHLNET” or “wholesale net”. The term “WHLNET” was used synonymously with WAC by First DataBank.

46. The AWPs and WACs relied upon by the State Medicaid programs have generally been those published nationally by (1) Thomson Publishing, publisher of the Red Book and various other price publications, (2) First Databank, publisher of the Blue Book and other electronic price publications; or (3) Medi-Span, Inc.[2], publisher of an electronic or automated price service and the Hospital Formulary Pricing Guide. Thomson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" or “Pricind Compendia” and their various publications and data services are hereinafter referred to as "Price Publications" or “Price Compendia Publications.”

47. CMS sets “Federal Upper Limit” (FUL) amounts limiting the maximum per-unit reimbursement any Medicaid Program may pay for certain multiple source drugs. CMS may impose a FUL on any multiple source drug if, in the aggregate:

a. All formulations of the drug have been evaluated as therapeutically

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[2]The Econolink software program available to the Relator from the wholesaler McKesson, but not available to government entities, provided Customers with AWPs, “Regular Prices” and Contract Prices for the Specified Drugs. The Contract Price represents the price generally and currently available in the marketplace for a particular drug to Customers. Attached as **Exhibit B** is an example of a print out from the Econolink software program. Customers, including the Relator, could easily calculate the potential profit or spread for dispensing a particular drug by using the information provided by the Econolink software program. AWPs available to the Customers in the Econolink software program were virtually the same as AWPs published by the pricing compendia, First DataBank and Medi-Span. Furthermore, the “Regular Price” available to Customers from the Econolink software program had a direct relationship to WAC and was generally a very small percentage more than the WACs published by First DataBank and Medi-Span. Although the prices published by First DataBank and Medi-Span were not always identical, any variance between the prices reported by the companies First Databank and Medi-Span is minimal.

equivalent by the FDA in the most current publication of *Approved Drug Products with Therapeutic Equivalence Evaluations*;

b. At least three (3) companies list their version of the drug and their prices in current national price publishing compendia; and

c. The above criteria are met, and the drug is available for sale nationally.

48. CMS sets the FUL for a drug meeting the above criteria at 150% of the price of the drug with the lowest reported price. That price then becomes the FUL for all manufacturers' forms of the drug, or the maximum per-unit amount a State Medicaid Program can pay for the drug.

VII. DEFENDANTS' SCHEME

A. SCHERING, SCHERING-PLOUGH AND WARRICK Operated as One Entity.

49. WARRICK was created in 1993 by SCHERING after much analysis and research by SCHERING/SCHERING-PLOUGH executives. SCHERING/SCHERING-PLOUGH knowingly and explicitly created WARRICK as a conduit through which SCHERING/SCHERING-PLOUGH ultimately perpetrated the fraud described herein. SCHERING created a separate "WARRICK" corporate name in order to label SCHERING "brand" drugs which no longer had patent protection and market exclusivity as "generic" "WARRICK" products. In sum, SCHERING/SCHERING-PLOUGH utilized WARRICK as a tool of SCHERING/SCHERING-PLOUGH to maximize SCHERING/SCHERING-PLOUGH profits for products that are no longer in exclusive "brand" markets and to allow SCHERING/SCHERING-PLOUGH to leverage purported generic WARRICK products,

such as the albuterol products at issue, in order to better market SCHERING/SCHERING-PLOUGH "brand" drugs.

50. WARRICK is a corporate fiction. Administratively SCHERING, SCHERING-PLOUGH and WARRICK operate as the same entity. WARRICK depends upon SCHERING/SCHERING-PLOUGH for all necessary business functions including: manufacturing, distribution, accounting and administrative departments for all of these internal functions. With a very small number of employees for sales and marketing, WARRICK's business offices are within the offices of SCHERING/SCHERING-PLOUGH and payroll is processed by SCHERING. WARRICK does not conduct its corporate business in Reno, Nevada as its letterhead represents. The Reno, Nevada address listed as WARRICK's headquarters on its letterhead is nothing more than a SCHERING-PLOUGH warehouse. WARRICK and SCHERING/SCHERING-PLOUGH use the same computer systems, telephone systems, employees, and centralized departments, and apparently use each other's letterhead interchangeably.

51. The companies acted as one, rather than as independent drug manufacturers. The marketing of SCHERING/SCHERING-PLOUGH drugs and WARRICK drugs is intermingled for the purpose of increasing the profits of SCHERING/SCHERING-PLOUGH. WARRICK employees marketed and sold SCHERING/SCHERING-PLOUGH products and SCHERING/SCHERING-PLOUGH employees marketed and sold WARRICK products. SCHERING/SCHERING-PLOUGH "leveraged" virtually free "generic" WARRICK products in order to better market SCHERING/SCHERING-PLOUGH brand drugs, such as Claritin, Proventil, Vancanese and Vanceril, without direct discounting. Also, WARRICK has offered customer rebates on sales of SCHERING/SCHERING-PLOUGH products.

The corporations' activities are so intermingled that WARRICK is not a distinct legal entity pursuing its own best interests, but rather is a mere marketing tool of SCHERING-PLOUGH and SCHERING.

B. The Fraud Scheme

52. The majority of DEFENDANTS' drugs, including the albuterol products specified in this Complaint, are distributed through drug wholesalers who resell and distribute the drugs to hospitals, pharmacies, physicians and clinics.

53. Mckesson Drug, Cardinal and Amerisource Bergen are wholesalers and have comprised a large part of the U.S. wholesale drug market during the relevant time period. Wholesalers generally sell to any health care provider (such as pharmacies, physicians and clinics) who can lawfully dispense or administer prescription drugs. The remainder of the wholesaler market comprised specialty wholesalers or distributors.

54. From at least on or before December 1994, and continuing through at least 2005, DEFENDANTS defrauded the United States by knowingly causing the Medicaid Programs to pay false or fraudulent claims for Albuterol Sulfate 0.083% and Albuterol Sulfate 0.5%.

55. The three specific drug products at issue with respect to DEFENDANTS are identified by "NDC" number as follows:

Drug Product	NDC
Albuterol Sulfate 0.083%, 3 ml, 60s	59930-1500-06
Albuterol Sulfate 0.083%, 3 ml, 25s	59930-1500-08
Albuterol Sulfate 0.5%, 20 ml	59930-1515-04

The specific drugs at issue are referred to jointly as the "Specified Drugs."

56. DEFENDANTS marketed and sold their products, including the Specified Drugs, to their Customers. The Customers purchased the products either directly from DEFENDANTS, through a GPO contract, or through wholesalers. When DEFENDANTS sold "generic" WARRICK product to wholesalers, they invoiced wholesalers at gross prices which DEFENDANTS referred to as wholesale acquisition cost prices, yet DEFENDANTS reported misleading, inflated WACs to the pricing compendia for the Specified Drugs.

57. The amount paid by a Customer was typically based on a price negotiated with DEFENDANTS, a price negotiated with a GPO, or an often equally competitive price set by a specialty wholesaler or distributor.

58. DEFENDANTS offered "contract pricing" to many of their customers that was less than "non-contract" or "Regular Cost" prices generally offered by wholesalers to any customer. Attached as **Exhibit B** is a printout from the Econolink software program for the wholesaler McKesson showing the AWP, Regular Cost and Contract Price. **Exhibit B** shows a "Regular Price" for Albuterol Solution .083%, NDC # 59930-1500-08 of $10.53 with an AWP of $30.25 for October 23, 2000. DEFENDANTS created inflated spreads on the Specified Drugs at issue for customers that purchased the drugs at Regular Cost, available to virtually any industry customer, and an even greater spread for those purchasing the Specified Drugs "under contract". Attached as **Exhibit C** is a print out for the Amerisource Bergen ECHO/Amerisource Select price data showing a Contract Price for all the NDCs at issue for the date of November 21, 2002. **Exhibit C** shows that on November 21, 2002, the Contract Price for Albuterol Solution .083%, NDC # 59930-1500-08 was $3.50 while the AWP was $30.25. Attached as **Composite Exhibit D** are invoices

for purchases of the albuterol solutions at issue from JJ Balan and ANDA which are specialty wholesalers or distributors. Prices available to the Relator from specialty wholesalers often were less than that of wholesalers and offered even greater "profit" or "spread" for the Specified Drugs.

59. Regardless of the method of purchase, DEFENDANTS' Customers submitted claims for payment to Medicaid when an albuterol solution was dispensed to a program beneficiary. The claims submitted by DEFENDANTS' Customers were paid at amounts directly influenced by DEFENDANTS' false and fraudulent prices.

60. DEFENDANTS disseminated false pricing information for the albuterol solutions to the Pricing Publications. DEFENDANTS knew that the prices it reported to the pricing compendia controlled the pricing compendia's report of AWP and WAC.

61. DEFENDANTS first reported false prices with respect to the albuterol solutions on or about December 1994. The reported prices did not represent prices actually being charged in the marketplace. Thereafter, DEFENDANTS' employees typically reported and/or confirmed the false and fraudulent prices to the Pricing Publications periodically. During the relevant time period between December 1994 and April 1996, DEFENDANTS falsely increased their AWPs on the albuterol 0.5% solution as shown in **Exhibit A**. Additionally, DEFENDANTS never updated or adjusted their initial price reports on the albuterol .083% or albuterol 0.5% to reflect prices being charged in the marketplace. Consequently, DEFENDANTS caused the price reporting compendia to publish false inflated WACs and/or AWPs from December 1994 through the present. For all the Specified Drugs, the prices actually being charged in the marketplace decreased and fluctuated with the marketplace.

62. DEFENDANTS knew that the prices they reported to the Price Publications directly affected reimbursement amounts paid by the Medicaid Programs. The false or fraudulent prices DEFENDANTS reported to the Price Publications caused inflated government reimbursement amounts on claims submitted by DEFENDANTS' Customers for the albuterol solutions at issue. Attached as **Exhibit A** is a chart setting out examples for each of the NDCs at issue showing: reported prices (AWP and WAC), relator cost and the corresponding spreads (difference between the prices at which DEFENDANTS actually sold their drugs and the false prices reported by DEFENDANTS). The prices listed as those available to the Relator, as a small volume infusion pharmacy, are some of the highest prices offered by DEFENDANTS in the marketplace. Therefore, the inflated spreads available to the Relator were some of the lowest spreads in the marketplace.

63. DEFENDANTS manipulated AWPs and WACs to induce their Customers to purchase DEFENDANTS' products, including the Specified Drugs, by marketing to their Customers the huge profits that would result to them. DEFENDANTS actively used the inflated spreads and huge profits as a marketing tool directed at providers to promote increased sales of the Specified Drugs. Moreover, the spreads, in effect, marketed themselves. Any purchaser could easily calculate the potential profit by using the reported prices and the actual sales price. For example, the inflated spreads were readily apparent from information on the ECHO program from Amerisource Bergen. See **Exhibit C.**

64. DEFENDANTS were well aware of how Medicaid used DEFENDANTS' reported pricing information to set reimbursement levels to providers for the Specified Drugs. At all relevant times, DEFENDANTS were aware that Medicaid used published

AWPs and/or WACs to estimate acquisition costs, defined as the best estimate of the price generally and currently paid by providers in the marketplace.

65. The Medicaid programs did not know of or sanction DEFENDANTS' conduct as set forth in this Complaint; i.e., the deliberate manipulation of their published prices to create inflated reimbursement spreads that would induce their Customers to purchase the Specified Drugs. DEFENDANTS never disclosed to the Medicaid programs their false price reporting practices.

66. DEFENDANTS' scheme to defraud the United States by causing inflated reimbursements for the Specified Drugs ran from at least December 1994 through 2005. Over that time period, Medicaid paid in excess of $304 million for the Specified Drugs (identified by 3 NDC numbers).

67. During the relevant time period, DEFENDANTS reported and/or confirmed the same false inflated WAC and AWP for the albuterol .083% drug products to the Price Publications while the actual prices at which DEFENDANTS sold albuterol .083% to their Customers decreased and fluctuated with the marketplace. Between December 1994 and April 1996, DEFENDANTS reported increased AWPs and WACs for albuterol 0.5% drug product to the Price Publications while the actual prices at which DEFENDANTS albuterol 0.5% to their Customers decreased and fluctuated with the marketplace. Thereafter, DEFENDANTS reported and/or confirmed the same false inflated WAC and AWP for the albuterol 0.5% drug product to the Price Publications while the actual prices at which DEFENDANTS sold albuterol 0.5% to their Customers decreased and fluctuated with the marketplace.

68. For example, DEFENDANTS' false and fraudulent price reporting on their

Abluterol Sulfate 0.083% 3mls, 25s, illustrates how they reported false and fraudulent prices. **Exhibit A** shows the following for DEFENDANTS' Abluterol Sulfate 0.083% 3mls, 25s: the reported AWP and WAC prices; the "Wholesaler List Price to Relator" (otherwise known as the "Regular Cost" or non-contract cost); the "Contract Price to Relator"; the "Price to Relator from a Specialty Wholesaler or Distributor"; and the corresponding dollar and percentage spreads created by DEFENDANTS' false price reports.

69. In July of 2001, the published AWP for DEFENDANTS' Abluterol Sulfate 0.083% 3mls, 25s, NDC # 59930-1500-08 was $30.25. The published AWP has remained at $30.25 from 1994 until the present. The price for Abluterol Sulfate 0.083% 3mls, 25s, NDC # 59930-1500-08, available to the Relator from a specialty wholesaler in July of 2001, was $4.09 and fell to $3.50 by March of 2003. In March of 2003, the difference (and potential profit) between the reported AWP price and the actual selling price for Abluterol Sulfate 0.083% 3mls, 25s was as great as $26.75 per package, or over seven and a half times the actual price at which DEFENDANTS sold the Abluterol Sulfate 0.083% 3mls, 25s to Customers such as the Relator.

70. Likewise, the reported WAC for DEFENDANTS' Abluterol Sulfate 0.083% 3mls, 25s was falsely inflated. The reported WAC for the albuterol solution remained at $24.75 from December 1994 to the present. The WAC spread on the Abluterol Sulfate 0.083% 3mls, 25s in March of 2001 was $21.25, or more than 6 times the actual price at which DEFENDANTS sold the Abluterol Sulfate 0.083% 3mls, 25s to Customers such as the Relator.

71. With respect to Medicaid reimbursement, the Specified Drugs, during most of the relevant time period, were multiple-source drugs subject to a FUL. Therefore, the

Medicaid reimbursement amount for such drugs has been capped at 150 percent of the reported price for the least costly therapeutically equivalent version of the drug, plus a reasonable dispensing fee. 42 CFR §447.331-333.

72. DEFENDANTS distorted the FUL pertaining to the Specified Drugs and other manufacturers' drugs affected by the same FUL by reporting false or fraudulent prices or fraudulently withholding pricing information about the Specified Drugs. Specifically, DEFENDANTS: 1) caused reimbursement for their Specified Drugs to be falsely inflated by the FUL amount less the lesser amount that would have been reimbursed had the EAC not been inflated; and 2.) caused reimbursement for all other manufacturers' drugs, that were reimbursed at FUL, in the FUL array to be falsely inflated by the amount of the FUL less the amount that the FUL would have been set at if DEFENDANTS had reported a truthful WAC, DP or AWP.

73. The Defendants thus caused the state's Medicaid programs to use an inflated FUL in each and every instance where the FUL would have been lower had the Defendants reported a truthful price or cost that would have caused the publishing of a price that, when multiplied by 150%, would have resulted in a lower FUL. Since HCFA/CMS used the lowest published price for drugs in the array to which the particular FUL was applied, the kinds of prices and costs that should have been truthfully reported by the Defendants for FUL purposes, included, but may not have been limited to, WAC, Direct Price, AWP, list prices and wholesale net.

74. DEFENDANTS fully controlled and manipulated the WACs and AWPs for the Specified Drugs to boost their sales at the expense of third party payors, including Medicaid.

75. From at least as early as 1994 through 2005, DEFENDANTS knowingly reported false and inflated prices to the price reporting compendia in order to fraudulently manipulate reimbursement for the entire list of Specified Drugs in **Exhibit A** and for the purpose of creating inflated spreads that it knowingly marketed to induce Customers to purchase their Specified Drugs. Approximately 11 million "NDC" specific prescription claims were paid or approved by State Medicaid programs for the Specified Drugs from 1994 through 2005, and each was caused to be false or fraudulent by the said false price reporting because EAC, and often FUL, had a material effect on the Government's determination of the amount to be paid and had a material effect on the Government's decision to pay the false or fraudulent claim.

76. Through its investigation and through its litigation in the instant action and in related state actions, Ven-A-Care has reviewed the DEFENDANTS' price reports to the Price Publications for the DEFENDANTS' drug products reimbursed by the states' Medicaid programs. Specifically, Ven-A-Care has investigated the Specified Drugs in **Exhibit E** and has alleged that the DEFENDANTS knowingly reported false, inflated prices for the Specified Drugs in **Exhibit E**. Ven-A-Care has investigated additional drugs marketed by the DEFENDANTS during the relevant time period. Those additional drugs are hereinafter referred to as "Schering Brand Drugs" and are listed in **Exhibit F**. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs because the DEFENDANTS did not materially misstate the drug price report for those drugs. Ven-A-Care has determined that the states' Medicaid programs did not incur substantial damages for the Schering Brand Drugs

because the DEFENDANTS caused AWPs to be reported that were within 25% of the Wholesaler's Acquisition Cost (subject to at most a 5% discount off of WAC) and thus did not materially misstate the drug price report for those drugs.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(l))

77. Plaintiff repeats and realleges ¶¶ 1 through 75 as if fully set forth herein.

78. DEFENDANTS knowingly presented or caused to be presented to the United States false or fraudulent claims, based on fraudulently manipulated and reported drug prices, for payment or approval.

79. By virtue of the false or fraudulent claims that DEFENDANTS made or caused to be made, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

80. DEFENDANTS are liable for FCA violations for each claim paid by a state Medicaid program on an NDC basis where a price reported or caused to be reported by a defendant was considered in the determination of EAC, or resulted in an inflated FUL, as well as for each and every submission by a State to collect, estimate or otherwise determine the federal matching for such NDC-based payments during the period encompassed by the Complaint.

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False
Records or Statements to Cause Claims to be Paid)
(31 U.S.C. § 3729(a)(2))

81. Plaintiff repeats and realleges ¶¶ 1 through 75 as if fully set forth herein.

82. DEFENDANTS knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government.

83. By virtue of the false records or false statements made by DEFENDANTS, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29,1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

84. Defendants are liable for FCA violations for each claim paid by a state Medicaid program on an NDC basis where a price reported or caused to be reported by a defendant was considered in the determination of EAC, or resulted in an inflated FUL, as well as for each and every submission by a State to collect, estimate or otherwise determine, the federal matching for such NDC-based payments during the period encompassed by the Complaint.

THIRD CAUSE OF ACTION

(False Claims Act: Presentation of False Claims;
Making or Using False Statements or Records;
31 USC §§ 3729(a)(1), (2); 42 USC 1320a-7(b)

85. Plaintiff repeats and realleges ¶¶ 1 through 75 as if fully set forth herein.

86. DEFENDANTS knowingly presented or caused to be presented to the United States false or fraudulent claims, based on fraudulently manipulated and reported drug prices, for payment or approval.

87. By knowingly using fraudulently manipulated and reported drug prices as inducements to purchase their Specified Drugs and seek from the Medicaid program inflated reimbursements from Medicaid, DEFENDANTS violated the False Claims Act by committing violations of the federal health care anti-kickback statute, 42 U.S.C. § 1320a-7b.

88. By virtue of the false or fraudulent claims that DEFENDANTS made or caused to be made, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

89. Defendants are liable for FCA violations for each claim paid by a state Medicaid program on an NDC basis where a price reported or caused to be reported by a defendant was considered in the determination of EAC, or resulted in an inflated FUL, as well as for each and every submission by a State to collect, estimate or otherwise determine, the federal matching for such NDC-based payments during the period

encompassed by the Complaint.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff and Relator Ven-A-Care of the Florida Keys, Inc., on behalf of the United States, demands and prays that judgment be entered in favor of the UNITED STATES against the DEFENDANTS, jointly and severally, as follows:

1. On each Cause of Action, for the amount of the United States' damages, trebled as required by law, and such civil penalties and interest as are required by law, together with all such further relief as may be just and proper.

2. The Relator requests that it receive an award from the proceeds of the action pursuant to 31 U.S.C.§3730(d), including an appropriate percentage of the proceeds of the action, and reasonable expenses necessarily incurred, plus reasonable attorneys' fees and costs.

DEMAND FOR JURY TRIAL

The Relator, on behalf of the United States, demands a jury trial in this case.

Respectfully Submitted,
Attorneys for Plaintiff,
Ven-A-Care of the Florida Keys, Inc.

/s/Alison W. Simon
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CERTIFICATE OF SERVICE

I hereby certify that I have this day, July 24, 2009, caused an electronic copy of the above to be served on all counsel of record via electronic mail service by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/Alison W. Simon
Alison W. Simon